

AGH Polystyrene		3	Trademark Appl. drug, \$	4-11-95	AGH
AGH Malanchuk (EPA)	1		Appl. drug, dec, IDS, \$	4-11-95	"
AGH Hamaguchi 1 (Niiz)	08/111,510		IFF	4-11-95	"
AGH Hamaguchi 1 (Niiz)	08/111,510		drugs (14)	4-11-95	"
AGH Wentze 1 (Hane)	08/035,073		Amnd, drugs	4-11-95	"
Emp Vynapel 2A (Colb)	08/111,014		Prin w/claim \$	4-11-95	AGH
Emp Subong 2 (Vioo)	07/852,206		PTR, decl, term decls, ex	4-11-95	"
Emp Gielon 1 (POLA)	1		App, dec, Bas #, 1449	4-12-95	AGH
AGH Mertens (Hane)	4		App, drugs.	4-12-95	"
Emp Lorgenecker (Blom)	5 PCT		App, drugs (14), Bas #	4-12-95	"
Emp Komirha 2 (Tomi)	08/190,447		Sub of References	4-12-95	"
Emp Meynussen 4 (Plou)	07/689,077		AF Amn w/text	4-12-95	"
Emp Classen 1 (Class)	08/104,539		Notice of Appeal	4-12-95	"
Emp Classen 1 (Class)	08/104,539		SMN AF Amn	4-12-95	"
Emp Klaus 1 (Brun)	08/050,184		Amendment w/text	4-12-95	"
Emp Sawasaki 11 (Angb)	08/148,917		IDS w/refs	4-12-95	"
Emp Miller 8A	08/284,298		Amendment w/2 exts	4-12-95	"
Emp Heads up 1	74/519,169		Communication	4-12-95	"
Emp Shah 8 (Kirb)	08/271,447		Amendment w/text	4-12-95	AGH
Emp Saira 1 (Take)	4,694,244		2nd MF	4-13-95	AGH
Emp Guibard 1A (LAIR)	07/945,575		IFF	4-13-95	AGH
Emp Hamaka 22 (ASAM)	5,036,937		1st MF	4-13-95	AGH
Emp Gorin 1 (Mack)	5,057,256		1st MF	4-13-95	AGH
Emp Baullou 1 (Rivo)	5,056,549		1st MF	4-13-95	AGH
Emp HIDA 6 (Yuan)	5,057,317		1st MF	4-13-95	AGH
Emp Kiguchi 1 (ONAK)	5,052,245		1st MF w/surcharge	4-13-95	AGH
AGH Chen 146 (Lien)	24/024,155		Response	4-13-95	AGH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1805
	)	
CLASSEN, J.B.	)	Examiner: VOGEL, N.
	)	
Serial No.: 08/104,529	)	Washington, D.C.
	)	
Filed: August 12, 1993	)	April 12, 1995
	)	
For: METHOD AND COMPOSITION	)	Atty's Docket: CLASSEN=1
FOR AN...	)	

NOTICE OF APPEAL FROM THE PRIMARY EXAMINER  
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the final rejection (or the rejection of claims for at least the second time), dated October 12, 1994 of the Primary Examiner. The claims appealed are 2-18, 21-35 and 37.

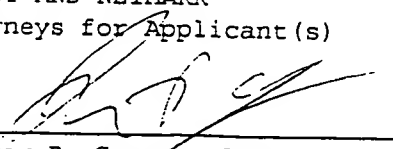
The item(s) checked below are appropriate:

- ☒ Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
- ☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
- ☒ The fee has been calculated as shown below:
- ☐ \$280.00
- ☒ \$140.00 (small entity)
- ☐ Not required (fee paid in prior appeal)

A three month-extension of time was petitioned and paid for on April 10, 1995.

- ☒ A check in the amount of \$140.00 is attached.  
(Check No. 8880)
- ☒ Please charge any deficit in the fee paid herewith to my Deposit Account No. 02-4035.

Respectfully submitted,  
BROWDY AND NEIMARK  
Attorneys for Applicant(s)

By   
Iver P. Cooper, Esq.  
Reg. No. 28,005

Telephone: (202) 628-5197  
Facsimile: (202) 737-3528  
IPC:lms

**BROWDY AND NEIMARK**

419 SEVENTH STREET, N.W.  
WASHINGTON, D.C. 20004

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DOCKET # CLASSE 1

PTO ID. # 08/104,529

*Antonia L. Lujan*

NON-NEGOTIABLE

APPLICANT(S) CLASSEN, J.B. (Clas) DKT. NO. CLASSEN=1  
SERIAL NO. 08/104,529 FILED August 12, 1993

THE PATENT AND TRADEMARK OFFICE  
STAMP HEREON ACKNOWLEDGES RE-  
CEIPT OF THE FOLLOWING PAPERS:

☒ FEES \$ 170.00 (CH. # EEEC)

☐ MISSING PARTS RESPONSE W/DECL.

☐ INVITATION TO CORRECT DEFECTS

☐ AMENDMENT

☐ RESPONSE

☒ NOTICE OF APPEAL

☐ APPEAL BRIEF (TRIPPLICATE)

☐ ASSIGNMENT

☐ EXTENSION OF TIME (\_\_\_\_ MONTHS)

☐ PRIORITY DOCUMENT(S)

☐ LETTER TO DRAFTSMAN

☐ VERIFIED STATEMENT(S) UNDER 37 CFR 1.9 AND 1.27

☐ OTHER \_\_\_\_\_

☐ DEMAND FOR CHPT. II

☐ ISSUE FEE TRANSMITTAL FORM

☐ DECLARATION UNDER § \_\_\_\_\_

☐ INFORMATION DISCLOSURE STATEMENT

☐ \_\_\_\_\_ SHEETS OF DRAWINGS

☐ TRANSMITTAL LETTER

☐ MAINTENANCE FEE LETTER

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SERIAL NO. 08/104,529 FILED August 12, 1993

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☐ RESPONSE

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☐ APPEAL BRIEF (TRIPPLICATE)

☐ ASSIGNMENT

☐ EXTENSION OF TIME (\_\_\_\_ MONTHS)

☐ PRIORITY DOCUMENT(S)

☐ LETTER TO DRAFTSMAN

☐ VERIFIED STATEMENT(S) UNDER 37 CFR 1.9 AND 1.27

☐ OTHER \_\_\_\_\_

☐ DEMAND FOR CHPT. II

☐ ISSUE FEE TRANSMITTAL FORM

☐ DECLARATION UNDER § \_\_\_\_\_

☐ INFORMATION DISCLOSURE STATEMENT

☐ \_\_\_\_\_ SHEETS OF DRAWINGS

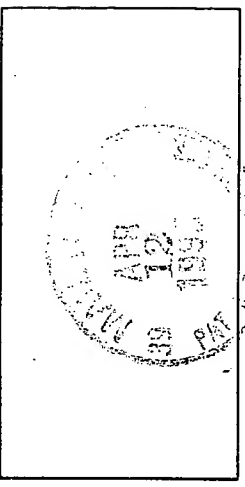
☐ TRANSMITTAL LETTER

☐ MAINTENANCE FEE LETTER

B&N-1



APPLICANT(S) CLASSEN, J.B. ( CLASS ) DKT. NO. CLASSEN=1  
SERIAL NO. 08/104,529 FILED August 12, 1993



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- ☐ ASSIGNMENT
- ☐ EXTENSION OF TIME (        MONTHS)
- ☐ PRIORITY DOCUMENT(S)
- ☐ LETTER TO DRAFTSMAN
- ☐ VERIFIED STATEMENT(S) UNDER 37 CFR 1.9 AND 1.27
- ☐ OTHER

- ☐ DEMAND FOR CHPT. II
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RESPONSE UNDER 37 CFR 1.116  
EXPEDITED PROCEDURE  
EXAMINING GROUP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

	ATTN.: NANCY VOGEL
In re Application of:	) Art Unit: 1805
	)
CLASSEN, J.B.	) Examiner: VOGEL, N.
	)
Serial No.: 08/104,529	) Washington, D.C.
	)
Filed: August 12, 1993	) April 12, 1995
	)
For: METHOD AND COMP-	) Docket No.: CLASSEN=1
OSITION FOR AN...	)

SUPPLEMENTAL AMENDMENT AFTER FINAL REJECTION

COURTESY COPY VIA FACSIMILE - (703-308-4312)

Honorable Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

S i r :

IN THE CLAIMS

Cancel claim 15.

In claim 37, line 19, as amended on April 10, 1995, replace "before" with --after--.

Please amend claims 22 and 28 as follows:

22 (amended). The method of claim 21 wherein said further administration

(a) comprises further administering to said mammal of at least 28 days of age but less than 175 days of age, at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen, wherein said at least one dose comprises a total of at least 4 separate pharmaceutically acceptable doses of at least one pharmaceutically acceptable immunogen from the group consisting of a diphtheria/tetanus/pertussis immunogen, a hepatitis B immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen, a polio immunogen, and a non-

USSN 08/104,529  
April 12, 1995

pediatric immunogen, administered to said mammal during said ages, at least 2 of said at least 4 doses provided prior to the age of 112 days of said mammal, and wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity of at least one chronic immune mediated disorder] of diabetes mellitis [, or at least one surrogate marker of said disorder,] in a population and/or subpopulation of said mammals.

28 (amended). In a method for pediatric immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age,

the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable suprainmunogenic dose of at least one pharmaceutically acceptable vaccine prior to the age of 112 days of said mammal,

wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity of at least one chronic immune mediated disorder] of diabetes mellitis [, or at least one surrogate marker of said disorder,] in a population and/or subpopulation of said mammals.

#### REMARKS

The Examiner is thanked for reviewing the AMENDMENT AFTER FINAL REJECTION filed April 10, 1995, and for bringing to Counsel's attention the imperfections addressed here. The Examiner indicated that the Amendment, with these additional corrections, appeared to fully address all rejections, but that she would have to review the case with her superior to determine

USSN 08/104,529  
April 12, 1995

if it were in condition for allowance.

Since the end of the statutory period has been reached, a notice of appeal is being filed on even date herewith to keep the application pending.

Respectfully submitted,

BROWDY AND NEIMARK  
Attorneys for Applicant

By: 

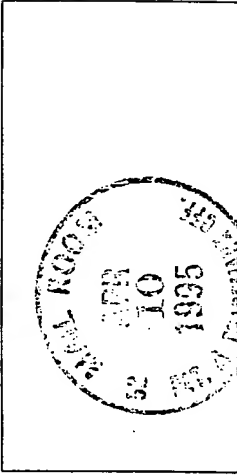
Iver P. Cooper  
Reg. No. 28,005

419 Seventh Street, N.W.  
Washington, D.C. 20004  
Telephone: (202) 628-5197  
Facsimile: (202) 737-3528  
IPC:lms

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AGH Aong 6	(Dire)	5,054,534	1st M-Fee	4-7-95	PER
AGH Tran 1.1	(Inf)	5,055,120	1st M-Fee	4-7-95	PER
AGH Margottreau 1	(Made)	5,054,634	1st M-Fee	4-7-95	PER
AGH Morel 7	(Made)	5,054,946	1st M-Fee	4-7-95	PER
AGH Mattiolo 1		5,054,953	1st M-Fee	4-7-95	PER
AGH Amirav 2	(Wolf)	5,055,677	1st M-Fee	4-7-95	PER
AGH Nishimoto 1.1	(Tsuk)	5,055,575	1st M-Fee	4-7-95	PER
AGH Kawamura 15	(Orak)	5,054,443	1st M-Fee	4-7-95	PER
AGH Sakai 1	(Saku)	07/501,900	IFF	4-7-95	PER
AGH Polsky 2	(Polis)	08/257,107	IFF	4-7-95	PER
AGH Byrne 1	(Dnx)	07/948,521	Expedited copy of asg.	4-7-95	PER
AGH Sakai 4	(Saku)	07/501,900	Drwgs.	4-7-95	PER
AGH Polsky 2	(Polis)	08/257,107	Drwgs.	4-7-95	PER
AGH Horikawa 1A	(Tsuk)	08/393,395	Notice of Incomplete Appln	4-7-95	PER
AGH Maute 2	(Lin)	5,054,719	2nd M-Fee	4-7-95	PER
AGH Mohss	(BER)	1	Appln, prelim, suppl., dis., SES dec, drwgs, \$	4-10-95	AGH
AGH Ygkota	(Yuas)	2	Appln, dec (Nat'l Stage)	4-10-95	AGH
AGH Jeppesen 1	(INTE)	29/032,130	Resp. to Request for Info, Prior Doc	4-10-95	AGH
AGH Lindgren 3	(Awap)	29/012,604	Amend., Terminal Disclaimer, \$	4-10-95	AGH
AGH Lindgren 4	(Awap)	29/012,605	Amend., Terminal Disclaimer, \$	4-10-95	AGH
AGH Aang 3	(Dire)	63	Appl., SES, dec, drwgs. (4), \$	4-10-95	AGH
AGH Concetti 1		08/140,396	Comm. Re Notice of Allowability	4-10-95	AGH
AGH Classen 1	(Clas)	08/104,529	Amnd., 3mth ext., \$	4-10-95	AGH
AGH Lagler 2	(Mage)	08/244,979	Comm. Re Small Entity Status	4-10-95	AGH
AGH Zick 1 PCT	(Yeda)	PCT/US94/13679	2nd Chang of Name of Applicant	4-10-95	AGH
AGH Gibboni 3 PCT	(Act)	PCT/US95/02431	Req. for Ext. of Time	4-11-95	AGH
AGH Chan	(PFT)	5	Des. Appl., drwgs., SES, dec, \$	4-11-95	"
AGH Masaki 65	(Saku)	08/301,816	Amnd	4-11-95	"
AGH Tanaka 50A		08/337,140	Amnd	4-11-95	"
AGH Paradis	(NYum)	1A PCT	PCT appl., drwgs., \$	4-11-95	"
AGH Bar-Shalom 1B	(Olou)	08/293,933	Amnd., 3 ext	4-11-95	"

APPLICANT(S) CLASSEN, J.B. (CLASS) CLASSEN=1  
SERIAL NO. 08/104,529 DKT. NO. FILED August 12, 1933



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- ☐ ASSIGNMENT
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- ☐ PRIORITY DOCUMENT(S)
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- ☐ OTHER \_\_\_\_\_

- ☐ DEMAND FOR CHPT. II
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**BROWDY AND NEIMARK**

419 SEVENTH STREET, N.W.  
WASHINGTON, D.C. 20004

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DOCKET # CLASS 10-1

PTO ID. # 08104,509

*Paul J. Jensen*

NON-NEGOTIABLE

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: CLASSEN, J.B.  
 Serial No.: 08/104,529  
 Filed: August 12, 1993  
 For: METHOD AND COMPOSITION FOR AN...

Art Unit: 1805  
 Examiner: VOGEL, N.  
 Washington, D.C.  
 Atty.'s Docket: CLASSEN=1  
 Date: April 10, 1995

THE COMMISSIONER OF PATENTS AND TRADEMARKS  
 Washington, D.C. 20231

**RESPONSE UNDER 37 CFR 1.116**

**EXPEDITED PROCEDURE**

**EXAMINING GROUP** \_\_\_\_\_ in

Sir:

Transmitted herewith is an [XX] Amendment [ ] \_\_\_\_\_  
 the above-identified application.

[XX] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.

[ ] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.

[ ] No additional fee is required.

The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)		Small Entity		Other Than a Small Entity	
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra		Rate	Additional Fee	Rate	Additional Fee
Total	33	Minus	37	=0		x11	\$	x22	\$
Indep.	11	Minus	15	=0		x22	\$	x76	\$
First Presentation of Multiple Dependent Claim						+120	\$	+240	\$
<b>TOTAL ADDITIONAL CLAIMS FEE</b>							\$	Total	\$

\* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col.1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity

Response Filed Within

[ ] First - \$ 55.00

[ ] Second - \$185.00

[XX] Third - \$435.00

[ ] Fourth - \$680.00

month after time period set

Other Than Small Entity

Response Filed Within

[ ] First - \$ 110.00

[ ] Second - \$ 370.00

[ ] Third - \$ 870.00

[ ] Fourth - \$1360.00

month after time period set.

[ ] Less fees (\$ ) already paid for month(s) extension of time on

[ ] Please charge my Deposit Account No. 02-4035 in the amount of \$ . A duplicate copy of this sheet is attached.

[XX] A check in the amount of \$ 435.00 is attached (check no. 8872).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR Section 1.16 and all patent processing fees under 37 CFR Section 1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR Section 1.18.

BROWDY AND NEIMARK  
 Attorneys for Applicant(s)

By:

IVER P. COOPER  
 Registration No. 28,005

Facsimile: (202) 737-3528  
 Telephone: (202) 628-5197

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1805	
	)		
CLASSEN , J.B.	)	Examiner: VOGEL, N.	
	)		
Serial No.: 08/104,529	)	Washington, D.C.	RESPONSE UNDER 37 C.F.R. 1.101
	)		EXPEDITED PROCEDURE
Filed: August 12, 1993	)	April 10, 1995	EXAMINING GROUP
	)		
For: METHOD AND COMP-	)	Docket No.: CLASSEN=1	
OSITION FOR AN...	)		

AMENDMENT AFTER FINAL REJECTION

Honorable Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

S i r :

IN THE CLAIMS

In claim 9, line 1, after "claim", insert --1--.

In claim 31, line 2, before "further administering",  
insert --(c)--.

In claim 32, line 2, before "administering", insert --  
(d)--, and at the end of the claim, add, --of step (c)--.

Please rewrite claims 3, 21, 23-27, 30, 33, 35 and 37 as  
follows:

3 (amended). [The method of claim 1] A method of  
immunizing a mammal less than 96 months of age against at  
least one infectious disease, while decreasing the incidence  
of diabetes mellitis, comprising

administering to said mammal one or more pharmaceutically  
acceptable pharmaceutical preparations, comprising one or more  
immunogens, according to an immunization schedule according  
to which, at specific times after birth, the mammal receives  
one or more pharmaceutically acceptable doses of one or more

immunogens;

said mammal thereby receiving, for each said infectious disease, a suitable immunogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease;

said administering further resulting in an immune response in said mammal sufficient to substantially reduce the incidence of diabetes mellitis in such mammals;

where, when all of the immunogens administered are selected from the group consisting of BCG, diphtheria, tetanus, pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, for at least one such immunogen, either

(a) a plurality of doses of the immunogen are administered, and such doses are administered less than 28 days apart, or

(b) the immunogen is a live polio virus and at least five doses are given during the first 112 days after birth, or

(c) the immunogen is not a live polio virus, and at least four doses are given during the first 112 days after birth.

21 (amended). In a method for immunization against at least three infectious diseases, comprising administering at least one pharmaceutically acceptable dose of diphtheria/tetanus/pertussis vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one

pharmaceutically acceptable dose of diphtheria/pertussis/tetanus vaccine, wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administering at least two doses of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal;

(2) administering said at least one of said dose of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal and also administering at least a second dose of said diphtheria/tetanus/pertussis vaccine, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering said at least one dose of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal and also administering as a total of at least four doses of said diphtheria/tetanus/pertussis vaccine prior to the age of 112 days of said mammal,

wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence [, prevalence, frequency, and severity of at least one chronic immune mediated disorder] of diabetes mellitis [, or at least one surrogate marker of said disorder,] in a population and/or subpopulation of said mammals.

23 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of

diphtheria/tetanus/pertussis vaccine and at least one pharmaceutically acceptable dose of hemophilus influenza vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one of a diphtheria/pertussis/tetanus vaccine and a hemophilus influenza vaccine wherein said further administration (a) is according to at least one method from the group consisting of

(1) administering at least one dose of both said diphtheria/pertussis/tetanus vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and at least a second dose of at least one said vaccine prior to 42 days of age of said mammal;

(2) administering at least one of said dose of both said diphtheria/tetanus/pertussis vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and also administering at least a second dose of both of said vaccines, wherein said second dose and or any subsequent dose is administered at less than 42 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering at least one of said dose of both said diphtheria/tetanus/pertussis vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and administering at least four doses, prior to the age of 112 days, of said mammal for said diphtheria/pertussis/tetanus vaccine or said hemophilus influenza vaccine, [wherein the further administration reduces [at least one measure

selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

24 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable first dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of a diphtheria/tetanus/pertussis immunogen, a polio immunogen, a hepatitis B immunogen, a hemophilus influenza immunogen, a non-pediatric immunogen, and a measles/mumps/rubella immunogen, to a mammal after 112 days of age but prior to 724 days of age, the improvement comprising

(a) further administering to said mammal, prior to the age of 112 days, at least one pharmaceutically acceptable second dose containing a greater amount of said immunogen than the amount of immunogen administered as said first dose after 112 days of age but prior to 724 days of age of said mammal, wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

25 (amended). In a method for immunization against at least two infectious diseases, comprising administering at

least one pharmaceutically acceptable dose of a non-whole cell pertussis vaccine to a mammal at least 42 days of age but prior to 724 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of an diphtheria/tetanus immunogen, a non-whole cell pertussis immunogen, a whole cell pertussis immunogen, a polio immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen and a non-pediatric immunogen, wherein said further administration (a) is according to at least one selected from the group consisting of

(1) administering said at least one dose of said immunogen at less than 42 days of age of said mammal;

(2) administering said at least one dose of said immunogen, said dose comprising at least a second dose, said second dose or any subsequent said dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering at least four doses prior to the age of 112 days of said mammal, wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

26 (amended). In a method for immunization against at

least two infectious diseases, comprising administering at least one pediatric vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable vaccine selected from (i) a combined vaccine containing at least diphtheria, tetanus, pertussis, and hemophilus influenza immunogens, and (ii) a combined vaccine containing at least diphtheria, tetanus, pertussis, and hepatitis B immunogens, wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administering at least one of said dose of said combined vaccine at less than 42 days of age of said mammal;

(2) administering at least one of said dose of said combined vaccine, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering at least four doses prior to the age of 112 days of said mammal, wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence [, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitus in a population and/ or subpopulation of said mammals.

27 (amended). In a method [of] for immunization against at least two infectious diseases and tolerizing against at least one antigen, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age and administering at least one tolerogen to said mammal, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of an diphtheria/tetanus/pertussis immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen, a polio immunogen, and a non-pediatric immunogen, wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administering said at least one dose of said immunogen at less than 42 day of age of said mammal;

(2) administering said at least one dose of said immunogen, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering at least four doses prior to the age of 112 days of said mammal, wherein the further administration reduces the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of

said disorder,] diabetes mellitis in a population and/ or subpopulation of said mammals.

30 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to said mammal prior to the age of 8 days; and

(b) further administering at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to said mammal at least 11 days of age but less than 26 days of age,

wherein the further administrations reduce the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

33 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to a mammal, the improvement comprising

(A) further administering at least a second pharmaceutically acceptable dose of at least one

pharmaceutically acceptable immunogen, said second dose and or any subsequent dose is administered less than 28 days after the preceding dose,

wherein said (i) second or any subsequent dose contains the same or different immunogens or the same or different amounts of said immunogens as any other dose; (ii) each said separate dose is administered during a 0-78 hour period, and (iii) the further administration reduces the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and or subpopulation of said mammals.

35 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of hepatitis B vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of said hepatitis B vaccine according to at least one step selected from the group consisting of

(1) administering at least 3 said doses of said vaccine at less than 56 days of age of said mammal;

(2) administering said at least one dose of said vaccine, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than

175 days of age; and

(3) administering at least four doses prior to the age of 112 days of said mammal, wherein the further administration reduces the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or of at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

37 (amended). A method of immunizing a mammal less than 96 months of age against at least two infectious disease and at least one chronic immune-mediated disorder, comprising

administering to said mammal one or more pharmaceutically acceptable pharmaceutical preparations, comprising one or more immunogens, according to an immunization schedule according to which, at specific times after birth, the mammal receives one or more pharmaceutically acceptable doses of one or more immunogens;

said mammal thereby receiving, for each said infectious disease, a suitable immunogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease;

said administering further resulting in an immune response in said mammal sufficient to substantially reduce the incidence [or severity] of [at least one chronic immune mediated disorder] diabetes mellitis in such mammal;

the first dose of said immunization schedule including an immune modulator beginning 42 days before birth,

where said mammal is not immunized with an immunogen in such amounts and at such times as would substantially induce [said immune-mediated disorder] diabetes mellitis.

#### REMARKS

1. The only substantive rejection in this case is against claims 2-18, 21-35 and 37, for insufficient enablement. However, the Examiner concedes that the disclosure is enabling for "a method [of immunizing] mammals which decreases the incidence of diabetes mellitis". In the interest of speedy resolution, Applicants have amended claims 3, 21, 23-27, 30, 33, 35 and 37 so that all pending claims are limited to the admittedly enabled indication. This is without prejudice or disclaimer to pursuing the subject matter in a continuing application.

2. Certain of the claims were also rejected for indefiniteness.

2.1 Claim 3 has been rewritten in independent form, hence, claims 2-18 are no longer dependent on cancelled claim 1.

2.2 Claim 9 has been amended to refer to claim 3.

2.3 The Examiner states that she is uncertain of what was intended by claim 32. However, the quoted language is from original claim 31, not 32, and does not reflect the correction of "proceeding" to --preceding-- in the last amendment.

An example or an immunization schedule within claim 31 is the following:

<u>Dose</u>	<u>Age</u>	
1	7 days	[see claim 30 (a)]
2	14 days	[see claim 30 (b)]
3	21 days	[ditto]
4	42 days	[see claim 31 and preamble of claim 30]

Dose 1 is given prior to the age of 8 days, and doses 2 and 3 between the ages of 11 and 26 days. The last dose at an age preceding 26 days of age was dose 3 at 21 days of age. Dose 4 was administered 21 days later, which is within the claimed interval of "at least 11 days, but less than 26 days".

Claim 32 would cover an administration schedule in which to the above schedule one added a dose 5 at age 63 days. This would be 21 days (i.e., between 11 and 26 days) after the "further administration" recited in claim 30.

To clarify these claims, we have inserted an identifying --(c)--, before the "additionally administering" at the beginning of the second line of claim 31, and an identifying --(d)-- before "administering" at the beginning of the second line of claim 32. In addition, at the end of claim 32, after "administration", we have added --of step (c)--.

It is respectfully concluded that the claims are now in  
condition for allowance.

Respectfully submitted,

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